UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

KAREN GUTHRIE, *individually and on behalf of the Estate of Donald Guthrie*,	)	
Plaintiff,	)	
v.	)	No. 1:11-cv-333-SKL
GREGORY BALL, M.D.,	)	
Defendant.	)	

ORDER

Before the Court is Defendant's "Motion in Limine #23 to Exclude FDA Alert from Evidence at Trial" [Doc. 137], in which Defendant seeks to exclude a warning letter ("FDA Alert") sent by the Federal Drug Administration ("FDA") to physicians regarding the dangers of fentanyl patches from evidence at trial. Plaintiff filed a timely response in opposition to Defendant's motion [Doc. 147], and Defendant filed a late reply [Doc. 203]. This motion is now ripe.

I. BACKGROUND

As reflected in multiple orders addressing a vast number of motions in limine filed by the parties, this is a healthcare liability action in which Plaintiff asserts negligence claims against Defendant for prescribing fentanyl patches for her late husband, Donald Guthrie ("Mr. Guthrie"). It appears to be undisputed that Mr. Guthrie's autopsy report indicates the cause of death resulted from fentanyl toxicity, but Defendant disputes this was the actual cause of death.

II. SUMMARY OF THE PARTIES' ARGUMENTS

In his motion, Defendant states that the FDA issued an FDA Alert to healthcare professionals regarding fentanyl transdermal patches, which were marketed as Duragesic and

generic brands. The FDA Alert at issue is attached to Defendant's motion [Doc. 137-1]. During the depositions of expert witnesses in this case, Plaintiff's counsel referenced and questioned the experts regarding the FDA Alert. Defendant contends that Plaintiff is relying on the FDA Alert to define the standard of care. Defendant argues that the FDA Alert should be excluded at trial because it (1) is irrelevant for purposes of defining the standard of care, (2) is inadmissible hearsay, and (3) would be unfairly prejudicial to Defendant and confusing to the jury.

First, Defendant argues that the FDA Alert is irrelevant to defining the standard of care in this case because Tenn. Code Ann. § 29-26-115(a) requires that each of the three basic elements of a medical malpractice action—standard of care, breach of the standard, and proximate cause—be proven by testimony of experts who were licensed and practicing in Tennessee or an adjacent state during the year preceding the date that the alleged injury or wrongful act occurred. Defendant therefore argues that the FDA Alert is not sufficient to prove standard of care, and cites authority that American Medical Association rulings do not establish the medical standard of care. *See Hartsell v. Fort Sanders Reg. Med. Ctr.*, 905 S.W.2d 944, 950 (Tenn. Ct. App. 1995). Defendant argues that federal law is clear that the FDA cannot intrude upon decisions statutorily committed to the discretion of healthcare professionals, and cannot prevent off-label use of drugs because to do so would interfere with the practice of medicine. Thus, Defendant contends that the FDA Alert does not define the standard of care and should be excluded.

Defendant also argues that the FDA Alert is inadmissible hearsay, to which no exception applies, including the 803(8) hearsay exception, because Defendant contends that the FDA Alert does not contain a statement identifying the office responsible for the alert or reflect the FDA's activities, does not indicate whether it pertains to a matter observed under a legal duty to report,

and does not appear to reflect actual findings from a legally authorized investigation. Defendant therefore argues that the FDA Alert should be excluded.

Finally, Defendant argues that evidence relating to the FDA Alert would be prejudicial to Defendant and confuse or mislead the jury. Because Defendant contends that the FDA Alert does not define the standard of care, as summarized above, Defendant argues that the introduction of the FDA Alert will only prejudice Defendant and confuse and mislead the jury.

In response to Defendant's motion, Plaintiff argues that the FDA Alert is admissible at trial because it consists of excerpts from the prescribing information, which is admissible in a Tennessee medical malpractice case. Plaintiff cites to case law for her argument that the FDA Alert should be admissible because "'a prescription drug's labeling or its PDR reference, when introduced along with other expert evidence on the standard of care, is admissible to assist the trier-of-fact to determine whether the drug presented an unacceptable risk to the patient.'" [Doc. 147 at Page ID # 2814 (quoting *Richardson v. Miller*, 44 S.W.3d 1, 16-17 (Tenn. Ct. App. 2000))]. Plaintiff argues that because the FDA Alert contains the same information, largely verbatim from the prescribing information, the FDA Alert should be admissible.

Plaintiff also argues that Defendant's reliance upon *Hartsell* is misplaced, because that case focused on whether the trial court had erred by excluding the AMA ethical opinion, and the case turned on the fact that the plaintiff had waived the error by failing to offer proof at trial. Plaintiff further argues that the admissibility of AMA ethical opinions has no bearing on the admissibility of the FDA Alert. Plaintiff further states that the other case relied upon by Defendant, *French v. Stratford House*, 333 S.W.3d 546, 561 (Tenn. 2011), which Defendant cited for the proposition that "it is improper to use alleged violations of federal and state regulations to prove a deviation in the standard of care as a component of a medical malpractice

claim," [Doc. 137 at Page ID # 2494], actually only holds that federal and state regulations are inadmissible in medical malpractice claims to prove negligence per se. Plaintiff states that the *French* holding did not apply to the plaintiff's ordinary negligence claims in that case, but rather only to the negligence per se claim. As Plaintiff's claims in the instant case are not based on a negligence-per-se theory, Plaintiff contends that the *French* case is inapplicable here.

Additionally, Plaintiff argues that the FDA Alert is admissible because it is relevant to cause of death. The FDA Alert was sent out to prescribing physicians because deaths had occurred when fentanyl was prescribed or used improperly. Plaintiff states that Defendant admitted he received and read the FDA Alert before he prescribed the fentanyl to Mr. Guthrie, but Defendant disputes that fentanyl toxicity caused Mr. Guthrie's death. Plaintiff argues that the FDA Alert is therefore relevant to cause of death and can be properly relied upon by Plaintiff's experts and used to cross-examine Defendant's witnesses.

Plaintiff also argues that the FDA Alert is not barred from evidence as hearsay because experts can rely on otherwise inadmissible evidence, including hearsay, under Rule 703 if it is reasonably relied upon by experts in the field. Plaintiff argues that the FDA Alert is also not barred as hearsay because it is not being offered for the truth of the matter asserted if the FDA Alert is offered to impeach Defendant and his experts or as a party admission, since Defendant has admitted he read the FDA Alert prior to prescribing the fentanyl patch to Mr. Guthrie. Additionally, Plaintiff argues that the FDA Alert is admissible under Rule 803(8) as a public records hearsay exception, and cites to case law where other courts have admitted FDA warnings. *See Musgrave v. Breg, Inc.*, No. 2:09-cv-01029, 2011 WL 4502032, at *6 (S.D. Ohio Sept. 28, 2011); *Toole v. McClintock*, 778 F. Supp. 1543, n.11 (M.D. Ala. 1991) (*rev'd*, 999 F.2d 1430 (11th Cir. 1993)) [hereinafter *Toole I*]; *Sabel v. Mead Johnson & Co.*, 737 F. Supp. 135 (D.

Mass. 1990). Plaintiff further contends that the FDA Alert will be established as a reliable authority through expert testimony, making it admissible under Rule 803(18)'s exception for learned treatises, periodicals, or pamphlets. Finally, Plaintiff contends that the residual exception under Rule 807 should result in the FDA Alert not being barred from admission as hearsay, because Plaintiff states that it would be hard to imagine a document with greater circumstantial evidence of trustworthiness than drug warning letters prepared by the FDA and sent to prescribing doctors, especially considering that Defendant and his expert have admitted under oath that they received and read the FDA Alert.

Plaintiff's last argument is that the probative value of the FDA Alert is not substantially outweighed by its prejudicial effect. Plaintiff cites to a Sixth Circuit case, *United States v. Gibbs*, 182 F.3d 408, 430 (6th Cir. 1999), stating that "'[u]nfair prejudice does not mean the damage to a defendant's case that results from the legitimate probative force of the evidence; rather it refers to evidence which tends to suggest decision on an improper basis.'" [Doc. 147 at Page ID # 2816]. Plaintiff also cites to *Musgrave*, 2011 WL 4502032, at *2, which found FDA warnings to be admissible over Defendant's arguments of unfair prejudice and relevance.

In Defendant's reply, he argues that Plaintiff's citation to *Toole I* should be disregarded because it was vacated and remanded by the Eleventh Circuit. Defendant also argues that the other cases cited by Plaintiff are distinguishable, because the FDA Alert in the instant case was not issued following a legally authorized investigation and it does not state it was based on reliable underlying data, such as peer-reviewed medical journals. Rather, Defendant states that the FDA Alert here is based on reports regarding patients who have had issues from fentanyl patches, but the FDA Alert does not specify who the reports were from or when they were made. Defendant also argues that the Rule 807 residual exception does not apply because Defendant

contends the FDA alert does not contain information that is more probative on the applicable standard of care in this case than the expert testimony provided. Defendant therefore argues that the FDA Alert is inadmissible hearsay.

III. ANALYSIS

Defendant's reply makes essentially two arguments: first, that the FDA Alert would not be admissible as a public records exception under Rule 803(8) because the cases cited by Plaintiff are either bad law, having been reversed, or are distinguishable; and second, that the Rule 807 residual exception does not apply to the FDA Alert. The Court will first address the parties' arguments regarding the admissibility of the FDA Alert under the public records exception of Rule 803(8) before turning to the parties' other arguments.

Rule 803(8) creates an exception to the hearsay bar for "[a] record or statement of a public office if: (A) it sets out: (i) the office's activities; (ii) a matter observed while under a legal duty to report . . . ; or (iii) in a civil case . . . , factual findings from a legally authorized investigation; and (B) the opponent does not show that the source of information or other circumstances indicate a lack of trustworthiness." Fed. R. Evid. 803(8). A public report should be admitted as a hearsay exception as long as it "contains factual findings and satisfies [the] trustworthiness requirement." *Sabel*, 737 F. Supp. at 142. Courts have held that FDA warnings, like the FDA Alert here, are admissible under the public records hearsay exception in Rule 803(8). *Musgrave*, 2011 WL 4502032, at *6 (citing *Toole I*, 778 F. Supp. 1543, n.11; *Sabel*, 737 F. Supp. 135). In *Musgrave*, the court refused to grant the defendant's motion in limine to exclude FDA statements, finding them to be relevant (at least for impeachment purposes), probative, and admissible hearsay as public records under Rule 803(8). Specifically, the court found that "[t]hese portions of the FDA bulletins fall within the hearsay exception defined by

Rule 803(8) because they are statements directly from the FDA 'setting forth matters observed pursuant to duty imposed by law as to which matters there was a duty to report.'" *Musgrave*, 2011 WL 4502032, at *6 (quoting Fed. R. Evid. 803(8)).

Regarding Defendant's first argument in his reply that *Toole I* should be disregarded, the Court notes that the Eleventh Circuit did in fact reverse and remand the case. *Toole v. McClintock*, 999 F.2d 1430 (11th Cir. 1993) [hereinafter *Toole II*]. However, while Defendant attempts to use *Toole II* to support his motion to exclude the FDA Alert in this case, the Court finds *Toole II* to be factually distinguishable from the instant case. In *Toole II*, the Eleventh Circuit found that the trial court erred in admitting an FDA document containing "the agency's proposal to require pre-market approval for silicone-gel filled breast prostheses," which included the FDA's "'proposed findings' on risks posed by the devices." *Id.* at 1434 (citing *General and Plastic Surgery Devices; Effective Date of Requirement for Premarket Approval of Silicone Gel-filled Breast Prosthesis, Proposed Rule*, 55 Fed. Reg. 20,568 (1990) (to be codified at 21 C.F.R. § 878) (proposed May 17, 1990)). The appellate court determined it was an abuse of discretion by the trial court to admit the FDA document because the report was irrelevant and failed to qualify for admission under Rule 803(8). Specifically, the court found that the document was irrelevant because it did not contain findings specifically about the implants at issue in the case, but rather proposed findings about implants generally. Additionally, the court noted that the report was proposed by the FDA years after the dates of the plaintiff's surgery. Thus, the court found the FDA document to be irrelevant and inadmissible due to timeliness. The Court also found that the FDA document was "not the kind of trustworthy report described in Rule 803" because the document "contained only 'proposed' findings," "invited public comment and

forecasted the issuance of a 'final' document after more study," and "Rule 803 makes no exception for tentative or interim reports subject to revision and review." *Id.* (citations omitted).

Here, the FDA Alert is relevant, as it specifically mentions the Duragesic patch (the brand of patch used by Mr. Guthrie) by name, and it was issued in 2007, years prior to Mr. Guthrie's treatment by Defendant in 2010. Additionally, the FDA Alert is not a proposed finding and does not invite public comment before final publication. Rather, the FDA Alert was sent to healthcare providers to reiterate the importance of prescribing and using fentanyl patches exactly as directed because the "FDA has continued to receive reports of death and life-threatening adverse events related to fentanyl overdose that have occurred when the fentanyl patch was used to treat pain in opioid-naïve patients . . . ." [Doc. 137-1 at Page ID # 2498]. There is nothing in the FDA Alert to indicate that it is a proposed or interim report, and thus Defendant's arguments that *Toole II* supports excluding the FDA Alert here fail.

Defendant next argues in his reply that *Musgrave* is distinguishable because the FDA bulletin in that case was issued following a legally authorized investigation, while the FDA Alert here was not, but the Court does not agree. Nothing in *Musgrave* indicates that the FDA was participating in any legally authorized investigation beyond its normal agency activities. In fact, the Court noted that the FDA's warning stated it was based on "chondrolysis reports," quoting from the report the statement that the "'FDA is reminding healthcare professionals that local anesthetics are not approved for intra-articular infusions, or for use in infusion devices like elastomeric pumps. Because of the chondrolysis reports, FDA is requiring the manufacturers of local anesthetic drugs to specifically warn against this use in the products' labeling. A similar warning will be required for elastomeric pumps.'" It appears that the FDA's warning in *Musgrave* and the FDA Alert here were both based upon adverse event reports submitted to the

FDA. *See* 21 C.F.R. §§ 803.30, 803.50, 310.305 (manufacturers have an obligation to report to the FDA any deaths or serious injuries reasonably believed to have been caused by a medical device and any unexpected adverse drug experiences caused by the use of a drug).

The Court is unpersuaded by Defendant's argument that *Musgrave* is distinguishable from the instant case, because there is nothing in the *Musgrave* decision to support that the FDA warning was based on anything more than "reports," just as in this case. While Defendant argues that the FDA Alert should be excluded because it was based only on "reports" it had received, Defendant does not provide any authority that "reports" are an insufficient basis. Furthermore, while some courts have found that expert testimony based upon adverse event reports is likely inadmissible as unreliable because such opinion testimony is not based upon sufficient facts and data, *see Golod v. La Roche*, 964 F. Supp. 841, 855 (S.D.N.Y. 1997); *Wade-Greaux v. Whitehall Labs.*, 874 F. Supp. 1441, 1481 (D.V.I. 1994), other courts have found that such adverse event reports are reliable and an adequate scientific basis for expert testimony, given that such reports are often the only data available, and they are widely relied upon by both the FDA and experts in the industry. *See Bartlett v. Mut. Pharm. Co., Inc.*, 678 F.3d 30, 39-40 (1st Cir. 2012) (*rev'd on other grounds*, 133 S.Ct. 2466 (2013)); *see also In re Heparin Prod. Liab. Litig.*, 803 F. Supp. 2d 712, 727 (citing *Glaser v. Thompson Med. Co.*, 32 F.3d 969, 972 (6th Cir. 1994) (noting that "[c]ourts also have expressed skepticism of causation opinions based solely on adverse event reports, case series, case reports and case studies, but have admitted such opinions when accompanied by other reliable scientific evidence"); *In re Gadolinium-Based Contrast Agents Prod. Liab. Litig.*, 956 F. Supp. 2d 809, 815 (N.D. Ohio 2013) ("It is entirely proper to use AERs [adverse event reports] to show that a drug manufacturer had notice of adverse events of the type suffered by plaintiffs in failure-to-warn claims) (collecting cases).

Defendant also argues that *Sabel* is distinguishable because that court found the opinions in an FDA letter to be admissible based on the reliable underlying data, including a peer-reviewed medical journal, and because the letter was a final opinion. The *Sabel* court noted that "[i]t makes no difference that the underlying data was collected by and received from an outside party, as long as the information was reliable." 737 F. Supp. at 142 (citing *Robbins v. Whelan*, 653 F.2d 47, 51 (1st Cir. 1981)). While the court did indeed find the FDA letter to be reliable because it relied upon a peer-reviewed medical journal article, and because it was a final opinion rather than a tentative conclusion, the court did not find reliance upon a peer-reviewed article to be a necessary requirement in establishing reliability. The court noted that there is no authority to support the limitation of Rule 803(8)'s public records exception to only epidemiological studies or accident investigations, because "no formal proceedings are necessary to satisfy the prerequisites of the rule." *Id.* (citing *In re Japanese Elec. Prod. Antitrust Litig.*, 723 F.2d 238, 268 (3d Cir. 1983)). Furthermore, the form of the record is not determinative of their admissibility, because the "indice of reliability for the governmental investigative report is the fact that it is prepared pursuant to a duty imposed by law." In *Sabel*, the FDA letter was based on an investigation into the association between Desyrel (an anti-depressant medication) and priapism (a health condition involving a prolonged, painful erection). Here, the FDA Alert was based on the FDA's investigation into adverse event reports which had been filed regarding the association between fentanyl patches, including Duragesic branded patches, with fatal respiratory depression from fentanyl overdose.

The Court does not find Defendant's arguments that the case authority cited by Plaintiff is distinguishable and/or supports excluding the FDA Alert. Instead, the Court finds that

Musgrave and *Sabel* support a finding that the FDA Alert is admissible as a public records exception to the hearsay bar under Rule 803(8).

The Court therefore **FINDS** that the FDA Alert is admissible under Rule 803(8)'s public records exception to the hearsay rule. Although it appears to the Court that there are other grounds argued by Plaintiff that would support admission of the FDA Alert for some purposes, because motions in limine may only be granted where the disputed evidence is inadmissible on all potential grounds, the Court need not address in detail the parties' arguments regarding the other methods by which the FDA Alert may be admissible. *See Bouchard v. Am. Home Prod. Corp.*, 213 F. Supp. 2d 802, 810 (N.D. Ohio 2002); *see also Malibu Media, LLC v. Pontello*, No. 13-cv-12197, 2014 WL 3528615, at *2 (E.D. Mich. July 16, 2014); *United States v. Afyare*, No. 3:10-cr-00260, 2013 WL 1386610 at *2 (M.D. Tenn. Apr. 4, 2013).

IV. CONCLUSION

Accordingly, for the reasons explained above, Defendant's "Motion in Limine #23 to Exclude FDA Alert from Evidence at Trial" [Doc. 137] is **DENIED**. The Court also notes that during the Final Pretrial Conference there was a discussion of a video issued by the FDA. Defendant stated the video was not produced in discovery. Plaintiff agreed that if she failed to produce the video in discovery, she would not seek to use the video during the trial in any way. Plaintiff will be held to this representation.

SO ORDERED.

ENTER:

s/ *Susan K. Lee*
SUSAN K. LEE
UNITED STATES MAGISTRATE JUDGE